UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

JESUS LOPEZ, JR., on behalf of the ESTATE OF JESUS LOPEZ, III, Plaintiff, vs. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., Defendants.	Case No.: **COMPLAINT FOR DAMAGES** **(1) NEGLIGENCE.** **(2) FAILURE TO WARN** **(3) MANUFACTURING DEFECT** **(4) DESIGN DEFECT** **(5) BREACH OF IMPLIED WARRANTY** **(6) BREACH OF EXPRESS WARRANTY** **DEMAND FOR JURY TRIAL**

COMES NOW the Plaintiff, JESUS LOPEZ, JR. ("Plaintiff"), on behalf of the ESTATE OF JESUS LOPEZ, III, ("Decedent"), pursuant to Tex. Civ. Prac. & Rem. Code § 71.021, by and through his undersigned counsel, and brings this Complaint against AngioDynamics, Inc. and Navilyst Medical, Inc. (collectively, the "Defendants"), and alleges as follows:

1. This is an action for damages arising out of the failure relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective implantable vascular access device sold under the trade name of Vortex TR Injectable Port (hereinafter "Vortex", or "Defective Device").

PARTIES

2. Plaintiff JESUS LOPEZ, Jr. is an adult resident of Concho County, Texas and claims damages as set forth herein.

3. Decedent, JESUS LOPEZ, III, was an adult resident of Concho County, Texas. Decedent died on May 12, 2021 and is survived by Plaintiff.

4. Defendant AngioDynamics, Inc. ("AngioDynamics") is a Delaware corporation with its principal place of business located in Massachusetts. AngioDynamics is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the Vortex.

5. Defendant Navilyst Medical, Inc. ("Navilyst") is a Delaware corporation with its principal place of business located in Marlborough, Massachusetts. Navilyst conducts business throughout the United States, including the State of Texas, and is a wholly owned subsidiary of AngioDynamics. Navilyst is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the Vortex.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

7. Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District and (b) Defendants' products are produced, sold to and consumed by individuals in the State of Texas, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

8. Defendants have and continue to conduct substantial business in the State of Texas and in this District, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this District, and made material omissions and

misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

9. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Texas, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

PRODUCT BACKGROUND

9. In 2003, a company called Horizon Medical Products ("Horizon") obtained clearance for the Triumph VTX Port with LiveValve Catheter under the 510(k) number K032557.

10. Shortly after the clearance of the Triumph port, Horizon merged with Rita Medical Systems, which was in the process of being acquired by Angiodynamics.

11. The Vortex port system bears a design and specifications that differ significantly from the Triumph port (including but not limited to the catheter design and connection hub), but Defendants represent to regulatory authorities that the Vortex port was cleared under the K032557.

12. Neither Horizon Medical Products nor Angiodynamics received clearance from the FDA to market the Vortex TR catheter, making such device *per se* misbranded pursuant to the Food, Drug and Cosmetic Act.

13. Defendants' Vascular Access Devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

14. The Vortex is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

15. According to Defendants, the Vortex is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

16. The intended purpose of the Vortex is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

17. The Vortex is a system consisting of two primary components: an injection port and a silicone catheter which includes additives intended to make it radiopaque.

18. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into a blood vessel.

19. The Vortex is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

20. The product's catheter is comprised of a polymeric mixture of silicone and a barium sulfate radiopacity agent.

21. Barium sulfate is known to contribute to reduction of the mechanical integrity of silicone *in vivo* as the particles of barium sulfate dissociate from the surface of the catheter over time, leaving microfractures and other alterations of the polymeric structure and degrading the mechanical properties of the silicone.

22. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[1]

23. The mechanical integrity of a barium sulfate-impregnated silicone is affected by the concentration of barium sulfate as well as the heterogeneity of the modified polymer.

[1] See Hecker JF, Scandrett LA. Roughness and thrombogenicity of the outer surfaces of intravascular catheters. *J Biomed Mater Res*. 1985;19(4):381-395. doi:10.1002/jbm.820190404

24. Upon information and belief, Defendants' manufacturing process in designing and constructing the catheter implanted in Plaintiff involved too high a concentration of barium sulfate particles for the polymer formulation, leading to improperly high viscosity of the admixed silicone before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix.

25. This defect in the manufacturing process led to a heterogeneous modified polymer which included weakened areas at the loci of higher barium sulfate concentration and led to fracture of the catheter.

26. Although the surface degradation and resultant mechanical failure can be reduced or avoided with design modifications (e.g. using a higher grade radiopacity compound and/or encapsulating the admixed polymer within an outer layer of pristine polymer), Defendants elected not to incorporate those design elements into the Vortex.

27. Additionally, at all times relevant, Defendants were on notice of a design defect in the Vortex which caused the failure of the locking mechanism which secures the catheter to the stem of the injection port.

28. As a result of this defect and resulting failure, the Vortex has an increased risk that the catheter will separate from the injection port, causing medication and administered fluids to leak into the tissue of the port implantation site.

29. Such leakage, also known as extravasation, can cause severe medical complications, including but not limited to induration, necrosis, or dehiscence of the implant incision; infection; permanent disfigurement; sepsis; or death.

30. Additionally, extravasation or other catheter failures during chemotherapy for cancer can impede the prescribed therapy, permitting the cancer to upstage, metastasize or otherwise advance.

32. At all times relevant, Defendants misrepresented the safety of the Vortex system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the Vortex system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

33. At all times relevant to this action, Defendants knew and had reason to know, that the Vortex was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to fracturing, migrating, perforating internal vasculature and otherwise malfunctioning.

34. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with a Vortex port had an increased risk of suffering life threatening injuries, including but not limited to: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; cancer advancement; tissue necrosis; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

35. Soon after the Vortex was introduced to market, which was years before Decedent was implanted with his device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Vortex was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that Vortex was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage.

b. cardiac/pericardial tamponade;

c. cardiac arrhythmia and other symptoms similar to myocardial infarction;

d. severe and persistent pain;

e. and perforations of tissue, vessels and organs; and

f. upon information and belief, even death.

36. In addition to the large number of AERs which were known to Defendants and reflected in

publicly accessible databases, there are many recorded device failures and/or injuries related to the Defendants' implantable port products which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

37. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[2]

38. Prior to the discontinuation of the ASR program, Defendants reported numerous episodes of failures of their implanted port/catheter products – including numerous episodes of catheter fracture – under the ASR exemption, thereby concealing them from physicians and patients.

39. Defendants were aware or should have been aware that the Vortex had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

40. Defendants also intentionally concealed the severity of complications caused by the Vortex and the likelihood of these events occurring.

41. Rather than alter the design of the Vortex to make it safer or adequately warn physicians of the dangers associated with the Vortex, Defendants continued to actively and aggressively market the Vortex as safe, despite their knowledge of numerous reports of catheter fracture and associated injuries.

42. Moreover, Defendants' warnings suggested that fracture of the device could only occur if the physician incorrectly placed the device such that undue catheter compression or "pinch-off" was allowed to occur. In reality, Defendants knew internally these devices were fracturing and causing serious injuries due to defects in the design, manufacturing and lack of adequate warnings.

43. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Decedent. Defendants had actual knowledge of the dangers presented by the Vortex System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Decedent, his prescribing physicians, or the public at large of

[2] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019)

these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; or

c. Recall the Vortex System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO JESUS LOPEZ, III

44. On or about June 26, 2019, Decedent underwent placement of the AngioDynamics Vortex port, Ref # PSAX-10-I, Lot # 5425431, at Texas Children's' Hospital in Houston, Texas for the delivery of cancer treatment.

45. Defendant, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the Vortex that was implanted in Decedent.

46. Defendant manufactured, sold, and/or distributed the Vortex to Decedent, through his doctors, to be used for delivery of chemotherapy.

48. On July 9, 2019, Decedent underwent surgery at Doctors Hospital at Renaissance in Edinburgh, Texas to remove the Vortex which was determined to be leaking chemotherapy medication into the subcutaneous tissues of the port implantation site due to catheter failure.

49. At all times, the Vortex was utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use and created procedures for implanting the product.

50. The Vortex implanted into the Decedent was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendant.

51. Decedent and his physicians foreseeably used and implanted the Vortex, and did not misuse, or alter the Vortex in an unforeseeable manner.

52. Defendants advertised, promoted, marketed, sold, and distributed the Vortex as a safe medical device when Defendant knew or should have known the Vortex was not safe for its intended purposes and that the product could cause serious medical problems.

53. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.

54. In reliance on Defendants' representations, Decedent's doctor was induced to, and did use the Vortex.

55. As a result of having the Vortex implanted, Decedent has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

56. Defendants' Vortex was marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and as a safer and more effective as compared to the traditional products and procedures for treatment, and other competing Vascular Access Devices.

57. The Defendants have marketed and sold the Defendants' Vortex to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

58. The injuries, conditions, and complications suffered due to Defendants' Vortex include but are not limited to hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; and even death.

59. Plaintiff brings this action pursuant to Tex. Civ. Prac. & Rem. Code § 16.064.

a) An action on the claims brought herein was first initiated in good faith on July 4, 2021, in the Superior Court for the Commonwealth of Massachusetts;
b) Such action was initiated within two years of Decedent's injury event and was, thus, timely filed;
c) Such action was dismissed for lack of personal jurisdiction on October 28, 2021;
d) The instant action is filed within sixty days of the aforesaid dismissal.

60. Despite diligent investigation by Plaintiff and Decedent into the cause of his injuries, including consultations with his medical providers, the nature of his injuries and damages, and their relationship to the Product was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Decedent's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

61. Plaintiff and Decedent did not learn of Defendants' wrongful conduct until a time within the applicable statute of limitations. Furthermore, in the existence of due diligence, Plaintiff and Decedent could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the product until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

62. Defendants were negligent toward Decedent in the following respects:

a) Defendant failed to design and establish a safe, effective procedure for removal of Vortex; therefore, in the event of a failure, injury, or complications it is difficult to safely remove Vortex.

b) Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using Vortex for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Decedent.

63. The Vortex was utilized and implanted in a manner foreseeable to Defendants.

64. The Vortex implanted into Decedent was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

65. At the time of his operation, Decedent was not informed of, and had no knowledge of the complaints, known complications and risks associated with Vortex.

66. Decedent was never informed by Defendants of the defective and dangerous nature of Vortex.

67. At the time of his implant, neither Decedent nor Decedent's physicians were aware of the defective and dangerous condition of Vortex.

68. At the time of the injuries referenced herein, Decedent did not know that the surgery he underwent was due to a defect in these products.

69. It was not until a time within the applicable statute of limitations, that Decedent discovered Defendants' wrongful conduct. Furthermore, Decedent could not have reasonably discovered the Defendants' wrongful conduct, including but not limited to, the defective design and/or manufacturing of these devices until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Decedent's suit was filed well within the statutory limitations period.

70. Decedent has suffered and will continue to suffer physical pain and mental anguish.

Decedent has also incurred substantial medical bills and has suffered loss of other monies due to the defective product that was implanted in his body.

FIRST CAUSE OF ACTION
NEGLIGENCE

47. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

48. The Defendants owed Decedent a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling and conducting post-market surveillance of the Vortex.

49. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test the Vortex before releasing the device to market, and/or failing to implement feasible safety improvements;

b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the Vortex;

c. Failing to conduct sufficient post-market testing and surveillance of the Vortex;

d. Designing, manufacturing, marketing, advertising, distributing, and selling the Vortex to consumers, including Decedent, without an adequate warning of the significant and dangerous risks of the Vortex and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

e. Failing to exercise due care when advertising and promoting the Vortex; and

f. Negligently continuing to manufacture, market, advertise, and distribute the Vortex after Defendants knew or should have known of its adverse effects.

50. As a direct and proximate result of the Defendants' actions, omissions and

misrepresentations, Decedent has suffered severe physical pain and injuries, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss as alleged herein.

51. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

52. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

53. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Vortex, including the one implanted into Decedent, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

54. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer the medications. Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

55. Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Vortex that was implanted into Decedent that the Vortex posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

56. Defendants further knew that these devices were fracturing and migrating for reasons other than "pinch-off" caused by the physician's initial placement of the device

57. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Vortex; no reasonable health care provider, including Decedent's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

58. The warnings, labels, and instructions provided by the Defendants at all time relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

59. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

60. The device, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

61. When Decedent was implanted with the device, Defendants Bard and BAS failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

62. Defendants intentionally underreported the number and nature of adverse events associated with dislodgement and migration of the devices to Decedent's health care providers, as well as the FDA.

63. Neither Decedent nor his health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

64. Decedent and his health care providers used Vortex in a normal, customary, intended, and

foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications directly into the patient's bloodstream. Moreover, Decedent's health care providers did not place or maintain the device incorrectly such that it caused the device to "pinch off" or otherwise malfunction.

65. Upon information and belief, the defective and dangerous condition of the device, including the one implanted into Decedent, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations. Upon information and belief, the device implanted in Decedent was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

66. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's injuries such that, had Defendants provided adequate warnings, Decedent and his physicians would not have used the device

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

67. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

68. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Vortex that was implanted into Decedent.

69. The Vortex implanted in Decedent contained a manufacturing defect when it left Defendants' possession. The device differed from said Defendants' intended result and/or from other ostensibly identical unites of the same product line.

70. Upon information and belief, the Vortex implanted in Decedent varied from its intended specifications.

71. Decedent and his health care providers used the Vortex in a way that was reasonably

foreseeable to Defendants.

72. The device's manufacturing defect was the direct and proximate cause of Decedent's serious physical injuries and economic damages in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

73. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

74. The Vortex implanted in the Decedent was not reasonably safe for its intended use and was defective with respect to its design.

75. The Vortex was in a defective condition at the time that it left the possession or control of Defendants.

76. The Vortex was unreasonably dangerous to the user or consumer.

77. The Vortex was expected to and did reach the consumer without substantial change in its condition.

78. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

79. As a direct and proximate result of the Vortex's aforementioned defects, the Plaintiff was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

80. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

81. Defendants impliedly warranted that the Vortex was merchantable and fit for the ordinary purposes for which it was intended.

82. When the Vortex was implanted in the Decedent, it was being used for the ordinary purposes for which it was intended.

83. The Decedent, individually and/or by and through his physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Vortex implanted in him.

84. Defendants breached these implied warranties of merchantability because the Vortex implanted in the Decedent was neither merchantable nor suited for its intended uses as warranted.

85. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective Vortex in the Decedent's body, placing said Decedent's health and safety in jeopardy.

86. The Vortex was sold to the Decedent's health care providers for implantation in patients, such as the Decedent.

87. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, the Decedent was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

88. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

89. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the Vortex was safe and fit

for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

90. The Vortex does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

91. At all relevant times, the Vortex did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

92. Decedent, his physicians, and the medical community reasonably relied upon the Defendants' express warranties for the Vortex.

93. At all relevant times, the Vortex was used on Decedent by Decedent's physicians for the purpose and in the manner intended by Defendants.

94. Decedent and Decedent's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

95. As a direct and proximate result of the breach of Defendants' express warranties, Decedent suffered severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein.

FRAUDULENT CONCEALMENT

96. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein. as if fully set forth herein.

97. Defendants fraudulently concealed information with respect to the Vortex in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the Vortex was

safe and fraudulently withheld and concealed information about the substantial risks of using the Vortex;

b. Defendants represented that the Vortex was safer than other alternative systems and fraudulently concealed information which demonstrated that the Vortex was not safer than alternatives available on the market;

c. Defendants concealed that it knew these devices were fracturing and migrating from causes other than the manner in which the implanting physician implanted the device; and

d. That frequency of these failures and the severity of injuries were substantially worse than had been reported.

98. The Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Vortex.

99. The concealment of information by the Defendants about the risks of the Vortex was intentional, and the representations made by Defendants were known by Defendants to be false.

100. The concealment of information and the misrepresentations about the Vortex was made by the Defendants with the intent that Decedent's health care providers and Decedent rely upon them.

101. Decedent and his physicians relied upon the representations and were unaware of the substantial risks of the Vortex which the Defendants concealed from the public, including Decedent and his physicians.

102. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Decedent suffered severe physical pain and injuries, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein.

103. The Defendants acted with oppression, fraud, and malice towards Decedent, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages

for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

104. Had Defendants not concealed this information, neither Decedent nor his health care providers would have consented to using the device in Decedent.

PUNITIVE DAMAGES

105. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the healthcare community and the general public, including Decedent and his health care providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the Vortex. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the implantation of said product, and intentionally downplayed the type, nature, and extent of the adverse side effects of being implanted with the device, despite Defendants' knowledge and awareness of the serious and permanent side effects and risks associated with use of same. Defendants further intentionally sought to mislead health care providers and patients, including Decedent and his health care providers, regarding the cause of dislodgement and migration failures of the device.

106. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Vortex caused serious physical side effects. Defendants continued to market said product by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the device, notwithstanding Defendants' knowledge of the true serious side effects of the Vortex, Defendants failed to provide accurate information and

warnings to the healthcare community that would have dissuaded physicians from surgically implanting the Vortex and consumers from agreeing to being implanted with the Vortex, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and implanting the Vortex.

107. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Decedent's implantation with Defendants' defective product, Decedent suffered the injuries and damages described in this complaint.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, special, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

a. Judgement be entered against all Defendant on all causes of action of this Complaint;

b. Plaintiff be awarded his full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;

e. Plaintiff be awarded punitive damages according to proof at the time of trial;

f. Awarding pre-judgment and post-judgment interest to the Plaintiff;

g. Awarding the costs and the expenses of this litigation to the Plaintiff.

h. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: December 27, 2021

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